

Mitchell E. Daniels, Jr. Governor

Judith A. Monroe, M.D. State Health Commissioner

DATE: December 30, 2009

TO: All Local Health Departments

Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

SUBJECT: Tylenol Arthritis Pain 100 Count with Ez-Open Cap

The following information has been received by our office from the U.S. Food and Drug Administration (FDA).

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Mcneil Consumer Healthcare Announces A Voluntary Nationwide Recall Of All Lots Of Tylenol® Arthritis Pain 100 Count With Ez-Open Cap

(Mon, 28 Dec 2009 17:12:00 -0500) In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is expanding its voluntary recall to include all available product lots of TYLENOL® Arthritis Pain Caplet 100 count bottles, with the distinctive red EZ-OPEN CAP (Full list of lot numbers provided below).

Company Contact:

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FOR IMMEDIATE RELEASE – December 18, 2009 – Fort Washington, PA – In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC,

Inc., is expanding its voluntary recall to include all available product lots of *TYLENOL® Arthritis Pain Caplet 100 count bottles, with the distinctive red EZ-OPEN CAP* (Full list of lot numbers provided below). In November 2009, 5 lots of this product were recalled due to consumer reports of an unusual moldy, musty, or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea. The recall is being expanded, as a precaution, to include all TYLENOL® Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP.

The uncharacteristic smell is caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. The source of 2,4,6-tribromoanisole is believed to be the breakdown of a chemical used to treat wooden pallets that transport and store packaging materials. The health effects of this compound have not been well studied, and to date all of the observed events reported to McNeil were temporary and non-serious.

Consumers who purchased TYLENOL® Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP from the lots included in this recall should stop using the product and contact McNeil for instructions on a refund or replacement. For these instructions or information regarding how to return or dispose of the product, consumers should call 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time) or log on to the internet at www.tylenol.com. Consumers who have medical concerns or questions should contact their healthcare provider. Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

The affected TYLENOL® Arthritis Pain Caplet 100 count product lot numbers can be found on the side of the bottle label. See the full list of affected product lot numbers below:

Recalled Product- Full List (LINK: http://www.tylenol.com/page2.jhtml?id=tylenol/news/subp_tar_recall.inc

UPC #	NDC Code#	Lot#	Product Description
0045- 0838- 21	8382100	07CMC011, 07DMC022, 07DMC024, 07FMC032, 07FMC033, 07GMC038, 07GMC039,07HMC045, 07HMC051, 07HMC053, 07JMC064, 07JMC069, 07JMC070, 07JMC071, 07XMC055, 07XMC058, 07XMC062, 08AMC002, 08AMC005, 08CMC026, 08DMC029, 08EMC037, 08EMC039, 08FMC044, 08FMC045, 08GMC050, 08GMC053, 08GMC063, 08GMC053, 08JMC103, 08JMC109, 08JMC110,	TYLENOL® ARTHRITIS PAIN CAPLET 100 COUNT BOTTLES (with red EZ-OPEN CAP)

08JMC111, 08KMC124, 08KMC127, 08KMC131, 08KMC132, 08XMC093, 08XMC094, 08XMC095, 09AMC010, 09CMC041, 09EMC075, 09EMC079, 09EMC076, 09GMC096, 09GMC097, 09GMC099, 09JMC118, 09JMC126, 09KMC133, 09KMC134, 09XMC114, 09XMC116

Only the TYLENOL® Arthritis Pain Caplet 100's with the distinctive red EZ-OPEN CAP are affected by this action. All other TYLENOL® Arthritis Pain products remain commercially available. McNeil Consumer Healthcare will reintroduce the TYLENOL® Arthritis Pain Caplet 100 count product by January, 2010 after moving production to a new facility.

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. markets a broad range of well-known and trusted over-the-counter (OTC) products around the globe. McNeil Consumer Healthcare is most widely recognized for the complete line of TYLENOL® acetaminophen products, the leading pain reliever brand in the adult and pediatric categories.